



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-3001]

Modified Risk Tobacco Product Applications for IQOS System with Marlboro Heatsticks, IQOS System with Marlboro Smooth Menthol Heatsticks, and IQOS System with Marlboro Fresh Menthol Heatsticks Submitted by Philip Morris Products S.A.; Closing of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; closing of comment period.

SUMMARY: The Food and Drug Administration (FDA) is announcing a closing date for the period for public comment on modified risk tobacco product applications (MRTPAs) submitted by Philip Morris Products S.A. for its IQOS system products. FDA recently received amendments to these MRTPAs and has made them available for public comment.

DATES: Submit either electronic or written comments by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure FDA considers your comment before completing its review of the applications.

ADDRESSES: You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring

that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2017-D-3001 for "Modified Risk Tobacco Product Applications for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks submitted by Philip Morris Products S.A." Received comments, those filed in a timely manner (see DATES), will be placed in the docket and, except for those submitted as

“Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 1-877-CTP-1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

## I. Background

In the *Federal Register* of June 15, 2017 (82 FR 27487), FDA published a notice of availability for MRTPAs submitted by Philip Morris Products S.A. for its IQOS products and gave the public 180 days to comment on the applications. FDA issued a subsequent notice in the *Federal Register* of November 22, 2017 (82 FR 55616), extending the period for public comment and announcing its intent to issue a notice in a future edition of the *Federal Register* announcing when the comment period will close. FDA recently received amendments to the MRTPAs and has made them available for public comment. In this notice, FDA is announcing that the period for public comment on these MRTPAs, including amendments, will close on [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FDA is required by section 911(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387k) (FD&C Act) to make an MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911(g) of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

In the event FDA receives additional amendments or otherwise needs to modify the comment period closing date, FDA will notify the public via the Agency's webpage for the MRTPAs (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. FDA does not intend to issue additional notices in the *Federal Register* regarding amendments or the comment period for these

MRTPAs. To receive email alerts, visit FDA's email subscription service management website (<http://go.fda.gov/subscriptionmanagement>), provide an email address, scroll down to the "Tobacco" heading, select "Modified Risk Tobacco Product Application Updates", and click "Submit". To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

## II. Electronic Access

Persons with access to the internet may access the application documents at:  
<https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm546281.htm>.

Dated: December 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-27807 Filed: 12/21/2018 8:45 am; Publication Date: 12/26/2018]